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September 22, 2023

**VIA ECF**

Hon. Thomas Vanaskie  
Special Master  
Stevens & Lee  
1500 Market Street, East Tower, 18th  
Floor  
Philadelphia, PA 19103

RE: *In re Valsartan, Losartan, and Irbesartan Products Liability Litigation*, No. 1:19-md-2875-RBK-KMW (D.N.J.)

Dear Judge Vanaskie:

I write on behalf of the Defendants' Executive Committee to inform the Court that defendants wish to address two agenda topics at the conference with the Court on September 26, 2023, and to set forth our positions on those items.

**I. Status Updates on Ongoing Negotiations Regarding End Dates for Losartan/Irbesartan Discovery**

**A. Aurobindo**

Defendants Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. (collectively, "Aurobindo") write to outline a disagreement with Plaintiffs regarding which Aurobindo custodians' files will be searched and produced through May 22, 2023 for purposes of irbesartan discovery. Although Aurobindo has negotiated agreement with Plaintiffs on many issues pertaining to search terms, custodians, and the Relevant Time Period, this single dispute remains. Aurobindo made another offer to resolve this issue today, which Plaintiffs' counsel have neither accepted nor rejected. As a result, Aurobindo does not believe this dispute to be ripe for the Court's attention as negotiations appear to be ongoing. Plaintiffs' counsel, however, has refused

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Aurobindo's proposal to defer this issue until the October 4 Case Management Conference given the Parties' ongoing negotiations. Accordingly, Aurobindo is prepared to argue this matter at the September 26 meeting and provides a summary for the Court below.

Aurobindo and Plaintiffs have aligned on the following list of 22 custodians whose custodial files will be searched through December 31, 2019, the large majority of whom were not custodians in valsartan discovery:

1. A. Vannur Reddy
2. Blessy Johns
3. C.V. Satyendranath
4. Dasarathi
5. Gattupalli Madhava Ramprasad
6. Govindarajan Narayanan
7. Hanumanthu Penchalaiah
8. Hemant Kumar Sharma
9. Jaipal Reddy
10. Kalakada Narasimha Reddy
11. Kurresambi Reddy
12. Madhusudhana Reddy
13. R. Nagaraju
14. Rajaeev TL
15. Ram Mohan A Rao ("Dr. Rao")
16. Ram Pravesh Singh
17. Shahid Siddiqui
18. Srinivas K. Rama
19. Subramanyam Maddala
20. Sudhakar Reddy Mandepudi
21. Swaminathan Srinivas
22. Vijay Kumar Handa

This number of custodians—22—is substantial, especially given the limited scope of Plaintiffs' irbesartan-related claims against Aurobindo. Those claims pertain solely to a very limited quantity of Aurobindo irbesartan API manufactured in 2016–2017 and recalled in 2018. That recall ended in 2018. In total, Plaintiffs' claims pertain to approximately \$200,000 in net sales of recalled Aurobindo irbesartan API, and they involve just one personal injury claimant against Aurobindo. Despite that narrow scope, Aurobindo agreed to a substantially larger number of custodians than Plaintiffs have demanded from other irbesartan/losartan manufacturers. These individuals cover the R&D, production, testing, and sale of allegedly contaminated irbesartan API by Aurobindo.

Accordingly, in negotiating the Relevant Time Period end date for general custodial discovery, Aurobindo argued that December 31, 2019 is the appropriate end date. That date is over a year after completion of Aurobindo's recall of irbesartan API, and is the end date Plaintiffs specified

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in their document requests. Instead of agreeing to that end date, which would be consistent with the approach taken in valsartan discovery, Plaintiffs insisted on an end date of May 22, 2023.

In light of this impasse, just before the September 12 Case Management Conference, Aurobindo offered a further compromise: while the generally applicable end date would stand as December 31, 2019, the Parties would meet and confer in good faith to identify a targeted subset of custodians who were involved in certain communications with FDA *after* that date, and Defendants would then search those custodians' files up through May 22, 2023 using targeted search terms tailored to that topic. Plaintiffs rejected that.

Instead, Plaintiffs demanded that the targeted group of custodians subject to an end date through May 22, 2023 would be searched using the full search term list, even though most of those terms are not tailored to the reason for the extended end date. Plaintiffs also reserved the right to request discrete sets of custodial documents beyond December 31, 2019, to complete any relevant email threads/discussions for a particular custodian that appeared to be cut off in the middle of relevant discussions as of December 31, 2019.

Aurobindo again, in the spirit of compromise, agreed to these more burdensome proposals, despite the limited nature of the claims against Aurobindo and the enormous volume of custodial files that already will be collected, processed, searched, reviewed, and produced.

Following this September 12 agreement, Plaintiffs have refused reasonable and proportional proposals regarding the custodial files to be searched through May 22, 2023—an end date that extends *nearly five years* after completion of the recall that forms the basis of Plaintiffs' claims against Aurobindo. Plaintiffs propose to include 13 custodians in this category—*over half* of the total number of custodians to which Plaintiffs and Aurobindo previously agreed for purposes of general discovery relating to irbesartan—and have never articulated any specific reason for including those custodians in particular, despite being repeatedly asked to do so many times over email and during a meet-and-confer.

In response, Aurobindo proposed five custodians to be searched through May 22, 2023: Blessy Johns (Aurobindo's US regulatory custodian), Dr. Rao (Chief Quality Officer; signed the response and updates thereto to FDA's 2022 FDA Warning Letter, to which Plaintiffs point as evidence of supposedly relevant communications with FDA postdating December 31, 2019), Sudhakar Reddy Mandepudi (President of Corporate QA), Jaipal Reddy (Assistant General Manager in Unit I QC; listed as participating in the investigation of one issue noted by FDA), and Srinivas K. Rama (Associate President Head Office-API; signed the Unit I action plan following the FDA Letter). Aurobindo noted the disproportionality inherent in proposing to include 13 custodians—a number that, on its own, already exceeds the total number of custodians being searched by other irbesartan/losartan manufacturers for all topics combined. Aurobindo further noted that it already produced FDA communications through September 2022 in irbesartan core discovery.

Plaintiffs refused this reasonable offer, insisting that they are entitled to nearly four years of additional custodial files for thirteen custodians because *some* of the 13 individuals *may* have

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been involved in internal discussions and activities responsive to ongoing FDA communications. Notably, however, those FDA communications do not pertain to allegedly contaminated irbesartan API or manufacturing processes resulting in alleged nitrosamine contamination. They do not even pertain to the Aurobindo irbesartan API that is the subject of the claims against Aurobindo in this MDL—not the economic loss claims, not the medical monitoring claims, and not the single alleged personal injury claimant. The FDA communications pertain to alleged manufacturing issues that occurred several years after the recall at issue in this litigation ended, and even longer after Aurobindo had ceased manufacturing or selling any irbesartan API alleged to contain nitrosamines.

In sum, while Aurobindo has been generous and conciliatory in its discovery negotiations with Plaintiffs to date, Plaintiffs' latest position is simply a bridge too far. Plaintiffs' position is untethered to the claims they pleaded against Aurobindo in this litigation and they offer no factual justification for each of the thirteen custodians they seek. Under any reasonable view of relevance and proportionality, Plaintiffs are not entitled to broad custodial discovery relating to manufacturing issues that pertain to an entirely different time period and do not involve alleged nitrosamine contamination of Aurobindo's irbesartan API.

Indeed, Aurobindo has already agreed to collect and search a substantial number of custodial files in this litigation, despite the very limited claims against it. Aurobindo's position in offering five custodians subject to an extended time period is eminently reasonable. For all of these reasons, Aurobindo respectfully requests an order that the May 22, 2023 extended end date applies only to the files of Blessy Johns, Dr. Rao, Sudhakar Reddy Mandepudi, Jaipal Reddy, and Srinivas K. Rama.

## **B. Hetero**

The Parties have conferred and Hetero agrees to the proposed end-date of December 31, 2019, for the Relevant Time Period for production. Hetero has agreed to extend that date until the present for five specific custodians, subject to change depending on particular custodians' involvement. The Parties have agreed to extend the Relevant Time Period for specific custodians at HeteroUSA and Camber involved in regulatory compliance and testing. Confirmation on those custodians is pending, and the Parties are still working together to identify those individuals.

## **C. Teva**

Teva and Plaintiffs have reached agreement regarding the end dates for custodial discovery as discussed at the September 12, 2023 Case Management Conference.

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**D. Torrent**

Torrent and Plaintiffs continue to meet and confer in good faith regarding the end date for collection of documents for Torrent custodians. To date, Torrent and Plaintiffs have reached agreement regarding the end date for collection for the following custodians:

1. Dawn Chitty
2. Bernadette Attinger
3. Saroja Garontla
4. Dhruvit Shah
5. Joshi Shubham
6. Paras Sheth
7. Kelly Gegenheimer
8. Prajyot Kulkarni
9. Anupama Siddhaye
10. Brijesh Patel
11. Swati Panwar
12. Sanjay Barhate

The parties are continuing to meet and confer regarding the end dates for the remaining custodians and will be prepared to address any outstanding disputes at the October 4, 2023 Case Management Conference.

**E. Vivimed**

Plaintiffs and defendant Vivimed Life Sciences Pvt. Ltd. agree that the company will search and produce documents to the present for custodians Nagesh Majeti, Chandran Tiruvattar, and Balu P, and through December 31, 2019 for all other custodians.

**F. ZHP Defendants**

Counsel for plaintiffs and the ZHP defendants are in the process of meeting and conferring regarding the discovery end dates for the various ZHP defendant custodians. The parties will be prepared to address any outstanding disputes at the October 4, 2023 Case Management Conference.

**II. Status Updates on CMO No. 32 Discovery Regarding Wholesaler and Retail Pharmacy Defendants**

**A. Retail Pharmacy Defendants**

The Retail Pharmacy Defendants understand from Plaintiffs that they do not intend to seek any relief with respect to Retail Pharmacy Defendants, but that they simply wanted to provide an update to the Court on our ongoing efforts. On or about August 21, 2023, the Retail Pharmacy Defendants produced supplemental dispensing data, which included consumer identifiers, TPP identifiers, and anticipated reimbursement amounts from those TPPs. The Retail Pharmacy

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Defendants will be producing additional data and providing interrogatory responses regarding profits and costs pursuant to CMO 32 and Special Master Order 83. Additionally, the Retail Pharmacy Defendants have proposed custodians and search terms to Plaintiffs and are negotiating the exact parameters of the targeted custodial discovery discussed in CMO 32.

**B. Wholesaler Defendants:**

Wholesaler Defendants have produced the pricing data responsive to CMO 32 sections 7.1.2 and 7.1.3. With respect to the costs and profits data referenced in section 7.1.1, at Plaintiffs' suggestion, Wholesaler Defendants continue to work to develop a potential proxy formula for approximating profit data regarding VCDs because, as they previously advised Plaintiffs and the Court, Wholesaler Defendants do not, in the ordinary course of business, calculate or maintain profit information on VCDs either on an NDC basis or individual transaction basis. In that regard, Wholesaler Defendants have been working with retained consultants to evaluate data and a potential proxy formula(s). Progress on this process is ongoing.

With respect to a schedule for the targeted discovery of Wholesaler Defendants' custodians regarding valsartan referenced in CMO 32 section 7.2, Wholesaler Defendants have proposed a scheduling order to Plaintiffs that includes a combined schedule for all custodial discovery regarding valsartan, losartan, and irbesartan. Given Plaintiffs' requests for discovery regarding losartan and irbesartan served on May 22, 2023, Wholesaler Defendants believe it is most efficient and cost effective to negotiate, conduct, and complete custodial discovery (which involves significant e-discovery efforts) at the same time and on the same schedule for all three products. Plaintiffs indicated they are agreeable to a simultaneous schedule for all three products in the proposed scheduling order Plaintiffs' counsel sent to Special Master Judge Vanaskie on August 30, 2023.<sup>1</sup> Moreover, as Plaintiffs acknowledged in their April 12, 2023 letter to the Court requesting targeted custodial discovery related to valsartan and plaintiffs' certified unjust enrichment claim, there is no pressing need to complete valsartan-related custodial discovery such that it would need to be completed separate or apart from custodial discovery on losartan and irbesartan.

Respectfully Submitted,



Jessica Davidson

cc: All counsel of record (via ECF)

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<sup>1</sup> Pursuant to the Special Master's rulings and directives at the hearing held on September 6, 2023, the parties continue to meet and confer regarding appropriate scheduling orders for Plaintiffs' discovery to Wholesalers regarding losartan and irbesartan and Defendants' discovery to Plaintiffs regarding losartan and irbesartan.